Experience of Nobori Stent Implantation for Bifurcation Coronary Lesions

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Drug-Eluting Stents

- **Cypher**
- **Taxus (Express)**
- **Endeavor**
- **Pico Elite**
- **Coroflex Please**
- **Xience V**
- **Promus Element**
- **Xience Prime LL, SV**
- **Resolute Integrity**
- **Biomatrix**
- **Nobori**
- **Genous**
Evaluation of Effectiveness and Safety of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice

**IRIS-DES Registry**

Consecutive PCI patients receiving New DES in 55 centers without a mixture of other DES

Prospective Enrollment

- **DESSIAN Registry**
  - Patents with CYPHER (N=3,000)
- **K-XIENCE Registry**
  - Patents with XIENCE (N=3,000)
- **IRIS-PRIME Registry**
  - Patents with XIENCE PRIME (N=2,000)
- **IRIS-NOBORI Registry**
  - Patents with NOBORI (N=1,000)
- **IRIS-BIOMATRIX Registry**
  - Patents with BIOMATRIX (N=1,000)
- **IRIS-ELEMENT Registry**
  - Patents with PROMUS ELEMENT (N=2,000)
- **IRIS-GENOUS-STEMI Registry**
  - STEMI with GENOUS (N=1,000)
- **IRIS-GENOUS-DM Registry**
  - DM Patents with GENOUS (N=300)

Clinical follow-up at 1-, 6-, and 12-months, and annually up to 5 years

**PI: Seung-Jung Park, MD, PhD**

**Funded by CVRF and Korean Ministry of Health and Welfare**
Inclusion Criteria

- Patients receiving Nobori (or other default DES) as the PCI devices.
- *No limitation of clinical or lesion characteristics*
- Agreement to the study protocol and informed consent

Limited Exclusion Criteria

- Patients with a mixture of other DESs
- Terminal illness with life expectancy <1 year
- Patients with cardiogenic shock
Study Outcomes

**Primary End Points**
Major cardiac adverse event (MACE); a composite of death, non-fatal MI, or TVR at 12 months post procedure.

**Secondary End Points**
- Death
- MI
- Composite of death or MI
- Repeat revascularization
- TVR
- Stent thrombosis (ARC criteria)
- Procedural success
IRIS-NOBORI Registry
From June 2010

- 586 patients were enrolled in 28 investigating sites in Korea
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>586 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, year</td>
<td>63.6 ± 10.7</td>
</tr>
<tr>
<td>Male</td>
<td>68.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>64.5%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>35.2%</td>
</tr>
<tr>
<td>Smoking</td>
<td>48.4%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>47.0%</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>1.4%</td>
</tr>
<tr>
<td>History of MI</td>
<td>5.4%</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>10.2%</td>
</tr>
<tr>
<td>Family history</td>
<td>4.0%</td>
</tr>
<tr>
<td>Prior heart failure</td>
<td>1.4%</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>7.7%</td>
</tr>
<tr>
<td>Peripheral disease</td>
<td>1.4%</td>
</tr>
</tbody>
</table>
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>586 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic renal failure</td>
<td>2.8%</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>2.8%</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>59.3 ± 9.0</td>
</tr>
<tr>
<td>Symptom</td>
<td></td>
</tr>
<tr>
<td>Stable angina</td>
<td>39.2%</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>31.7%</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>17.8%</td>
</tr>
<tr>
<td>STEMI</td>
<td>11.3%</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>1 vessel</td>
<td>59.2%</td>
</tr>
<tr>
<td>2 vessel</td>
<td>27.2%</td>
</tr>
<tr>
<td>3 vessel</td>
<td>13.3%</td>
</tr>
<tr>
<td>Left main</td>
<td>2.1%</td>
</tr>
</tbody>
</table>
## Procedural Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>586 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target lesion</strong></td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>58.6%</td>
</tr>
<tr>
<td>LCX</td>
<td>24.9%</td>
</tr>
<tr>
<td>RCA</td>
<td>29.3%</td>
</tr>
<tr>
<td>Left main</td>
<td>1.3%</td>
</tr>
<tr>
<td>IVUS guidance</td>
<td>90.8%</td>
</tr>
<tr>
<td>Urgent procedure</td>
<td>16.2%</td>
</tr>
<tr>
<td>Use of IABP</td>
<td>3.2%</td>
</tr>
<tr>
<td>Number of stents per patients</td>
<td>1.4 ± 0.8</td>
</tr>
<tr>
<td>Length of stents per patients, mm</td>
<td>33.8 ± 21.1</td>
</tr>
</tbody>
</table>
Nobori in Bifurcation Lesions

• **106 patients (18.7%)** had bifurcation lesions with side branches > 1.5 mm which were treated with Nobori stents.

• 1-year outcomes will be available at the end of this year.

• The outcomes will be compared with others DES in all patients and subgroups including bifurcation lesions.
Selection of Stent for Bifurcation

- Strut width and thickness
- Potential stent deformation
- Conformability
- Diameter of the open cell
- Comparative results with other DESs
Open Cell Diameter of Nobori Stent

2.9 mm in 3 mm Nobori stent
3.0 mm in 3.5 mm Nobori stent

Courtesy Dr. Lefevre and Dr. Serra
Case Examples
CROSS & PERFECT Trials in Korea

to assess IVUS-Guided Bifurcation Stenting

CROSS

Coronary bifurcation lesions

Side branch stenosis < 50%

Single Stent cross-over

If, Poststenting SB stenosis ≥ 50%

Randomization

Leave alone

PERFECT

Side branch stenosis ≥ 50%

Randomization

Provisional T

Crushing

Kissing balloon inflation

TAP

If, SB TIMI ≤ 2, or Dissection ≥ C

PI: Seung-Jung Park, MD
Choice of optimal strategy for bifurcation lesions with normal side branch

CROSS Trial
Bifurcations without SB Stenosis

MEDINA Class

proximal
distal

1:0:0 0:1:0 1:1:0 1:1:1 0:0:1 1:0:1 0:1:1
1. Treatment at the operator’s discretion

2. FFR in SB (selected sites)

1. IVUS exam in MV
2. FFR in SB (selected sites)

1. Provisional T stenting in SB *
2. IVUS in both branches

Leave it alone group (N=150)

2nd Randomization

• Stratified by sites

Kissing balloon group (N=150)

1. FFR in SB before kissing balloon
2. Rewire into SB
3. Kissing balloon inflation

SB DS ≥ 50% & TIMI 3 flow

TIMI ≤ 2 flow

SB DS < 50% & TIMI 3 flow

1. IVUS exam in MV
2. FFR in SB (selected sites)

1. IVUS exam in MV
2. FFR in SB (selected sites)
3. Provisional T stenting in SB *

* The decision can not be influenced by the value of FFR.
OPtimal StEnting StRategy For TruE BifurCaTion

PERFECT Trial

Bifurcations with SB Stenosis

MEDINA Class

- 1:0:0
- 0:1:0
- 1:1:0
- 1:1:1
- 0:0:1
- 1:0:1
- 0:1:1
1. Preprocedural IVUS in both branches
2. Predilation in the MV
3. MV stenting while keeping jailed wire in the SB
4. Rewire into the SB
5. Kissing balloon inflation with low pressure at SB

1. Postprocedural IVUS in both branches
2. T stenting with minimal protrusion into MV
3. Sequential high pressure balloon dilatation in both in-stent areas
4. Kissing balloon inflation
5. Postprocedural IVUS in both branches

Angiography at SB
- TIMI 3 flow
- DS < 70%
- Dissection ≤ class B

Final single-stent

Crossover to crush
Serious dissection necessitating urgent stenting in SB after predilation*

Angiography at SB
- TIMI ≤ 2 flow or
- DS ≥ 70% or
- Dissection ≥ class C

Final two-stent

Preprocedural IVUS in both branches
Predilation in the MV
MV stenting while keeping jailed wire in the SB
Rewire into the SB
Kissing balloon inflation with low pressure at SB

Crush group (N=240)

Provisional T stenting group (N=240)

Randomization with any DES

Wire insertion into both branches

* Predilation in SB is strongly discouraged.
Case 1: Bifurcation Stenosis
IVUS Evaluation

Side branch (3 mm vessel)
- Distal
- Bifurcation

Main branch (4.5 mm vessel)
- Distal
- Bifurcation
- Proximal
Provisional Stenting Strategy

Compliant Balloon 2.5mm

1st Nobori 3.5X23 mm

Stent Balloon
Provisional Stenting Strategy

2nd Nobori 3.5x18mm

Non-compliant B 3.5mm
After Main Branch Stenting
FFR Assessment
Kissing Balloon Inflation

Compliant 2.5 mm  NC 3.5 mm  Kissing balloon
FFR and Angiograms
## Final IVUS in LAD

<table>
<thead>
<tr>
<th>Distal segment</th>
<th>Bifurcation</th>
<th>Proximal segment</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1 mm²</td>
<td>9.4 mm²</td>
<td>10.5 mm²</td>
</tr>
</tbody>
</table>
Case 2 : True Bifurcation
IVUS Evaluation

Distal segment | Bifurcation | Proximal segment

LAD

1st Diag. | 2nd Diag.

Bifurcation (2.5 mm) | Bifurcation (2.5 mm)
Planning

Crossover

Crush
Finals without Touch for the 1st Diag.
Final IVUS Evaluation

LAD

Distal  Bifurcation  Proximal  Proximal

8.7 mm²  8.9 mm²  10.5 mm²  9.6 mm²

2nd Diag.

Distal  Bifurcation

5.8 mm²  5.4 mm²
Final Angiograms
Conclusion

• Nobori stent with open cell and larger side branch access makes procedure safe and successful in PCI for bifurcation lesions.

• Nobori stent may be a good option for bifurcation lesions treated with either single- or two-stent strategies because of its procedural feasibility and favorable long-term safety and efficacy.